K063876

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Medivators Reprocessing Systems Modular Disinfection System
for Endoscope Reprocessing

510(k) Summary of Safety and Effectiveness

JUN 14 2007

Manufacturer:	Medivators Reprocessing Systems, a Division of Minntech Corporation
Address:	14605 28th Avenue North Mpls., MN 55447 USA
Official Contact:	Lynn Lueders Director, Regulatory Affairs

Medivators has supplied the following information to the U.S. Food and Drug Administration to support substantial equivalence of the Medivators Reprocessing Systems Modular Disinfection System (MDS) for Endoscope Reprocessing to other endoscope reprocessors currently marketed in the U.S.

1. Device Description

The Modular Disinfection System (MDS) is an electro-mechanical system intended to test and high level disinfect heat sensitive semi-critical endoscopes. It is not intended for reprocessing rigid endoscopes. The machine can use any FDA cleared, reusable liquid germicide which is on the market that is labeled for high level endoscope disinfection. The testing provided to the FDA used both Medivators Rapicide® High Level Disinfectant and Cidex® OPA High Level Disinfectant.

The MDS does not replace manual cleaning of endoscopes, they must be precleaned and cleaned according to the endoscope manufacturer's instructions and professional guidelines prior to reprocessing them in the MDS.

During its software based reprocessing cycle, the machine tests the endoscopes for leaks and blockages. Before and during the machine cycles, connectivity with the machine through the connector blocks is evaluated. If the scopes pass these tests, they are flushed with water and detergent, disinfected and rinsed. The disinfection cycle takes approximately 30 minutes. The MDS is capable of asynchronously reprocessing two scopes at a time.

The machine has many built in safety features which stop the cycle and alarm when certain conditions exist which could indicate that disinfection might be compromised. These alarms and causes are defined in the directions for use for the product.

The machine also prints records by endoscope serial number indicating the results of testing, disinfection, number of disinfections, etc. which are required for permanent records.

2. Intended Use

Medivators Reprocessing Systems Modular Disinfection System (MDS) for Endoscope Reprocessing tests, disinfects and rinses flexible endoscopes, such as fiberoptic and video endoscopes between patient uses. The MDS is indicated to provide high level disinfection of heat sensitive semi-critical endoscopes. It is indicated for use with FDA cleared, liquid high level disinfectants.

The MDS does not replace manual cleaning of endoscopes, they must be precleaned and cleaned according to the endoscope manufacturer's instructions and professional guidelines prior to reprocessing them in the MDS.

3. Comparison to Another Device in Commercial Distribution Within the United States

The MDS is equivalent in function and indications to the Medivators DSD-91E™ Endoscope Disinfector. This machine was found to be substantially equivalent in 1994 (K914145). Both machines have the same indications for use, the same methods of providing disinfection, can use the same reuseable disinfectants at the same temperatures and times. Both machines can reprocess two scopes asynchronously, one in each bay.

4. Summary of Testing

Medivators has provided testing to show that the MDS is safe and effective for its intended use following the requirements listed in the FDA's Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities (dated August 1993).
This testing included:

Efficacy Testing

The MDS was tested using standard methods defined by the FDA guidance document. This testing included simulated use and in use testing.

The simulated use testing showed a $>10^6$ log reduction in the organism *Mycobacterium terrae* after the endoscopes were reprocessed in the MDS.

In use testing showed no viable organisms remained on the endoscopes following the disinfection cycle.

Additional in-use testing was performed to show that the MDS provided disinfected endoscopes when exposed to the entire endoscope cycle of disinfecting and rinsing.

Material Compatibility

The effect of disinfectants (Rapicide and Cidex OPA) on the materials used in the MDS was evaluated and showed that the materials had no significant deterioration over their use life. Studies were also presented to show that the filters used in the water filtration system were compatible with common disinfectants.

Biocompatibility

The amount of disinfectant residue left on endoscopes and in the MDS after the disinfection and rinsing cycles was evaluated and compared to determined safe levels. The results of the testing showed that any remaining residues would not have an effect on patients or users of the machine.

Performance Data

Data was provided to the FDA to show that the machine performs as required. This evaluation included testing to show that the leak check, blockage check, connectivity checks, disinfection cycle, rinse cycles, and drying cycles performed correctly. Any error messages were tested to ensure they function properly to notify users of any possible failure modes. Testing was performed to show that all critical parameters of the machine function correctly.

Testing was presented that showed that disinfectants which require heating remained at their required temperature for the length of time required in the labeling for the disinfectant.

Testing was completed that showed that the MDS self disinfection cycle works properly by disinfecting all areas of the machine, including the water filtration system.

Studies were performed to show that the water filtration system will function appropriately over time and that the machine will alarm if water filters are plugged to a point which will lower the water pressure below required input. This study also showed that the filters remained bacterial retentive even when plugged to a point that causes the machine to alarm.

5. Summary of Substantial Equivalence

Minntech Corporation has provided the above information in the form of a 510(k) to support the claim that the MDS is safe and effective when used in accordance with the device labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

Medivators Reprocessing Systems
C/O Ms. Lynn Lueders
Director, Regulatory Affairs
A Minntech Corporation Business Group
14605 28th Avenue, North
Minneapolis, Minnesota 55447-4822

JUN 14 2007

Re: K063876
Trade/Device Name: Medivators Reprocessing Systems Modular Disinfection System for Endoscope Reprocessing
Regulation Number: 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FEB
Dated: May 6, 2007
Received: June 7, 2007

Dear Ms. Lueders:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if Known): K063876

Device Name: Medivators Reprocessing Systems Modular Disinfection System for Endoscope Reprocessing

Indications for Use:

Medivators Reprocessing Systems Modular Disinfection System (MDS) for Endoscope Reprocessing tests, disinfects and rinses flexible endoscopes, such as fiberoptic and video endoscopes between patient uses. The MDS is indicated to provide high level disinfection of heat sensitive semi-critical endoscopes. It is indicated for use with FDA cleared, liquid high level disinfectants.

The MDS does not replace manual cleaning of endoscopes, they must be precleaned and cleaned according to the endoscope manufacturer's instructions and professional guidelines prior to reprocessing them in the MDS.

Prescription Use ____ AND/OR Over-the Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Geetha Jayan - for Sheila Murphey

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K063876